

Application No.: 10/021,294

Docket No.: CTCH-P01-014

**IN THE CLAIMS**

1-4. (cancelled)

5. (previously presented) A composition comprising:

a cyclodextrin-containing polymer,

a therapeutic agent, and

a complexing agent, comprising:

at least one guest moiety that forms an inclusion complex with a host moiety of said

cyclodextrin-containing polymer, wherein the guest moiety is selected from

adamantyl, naphthyl, cholesterol, and combinations thereof, and

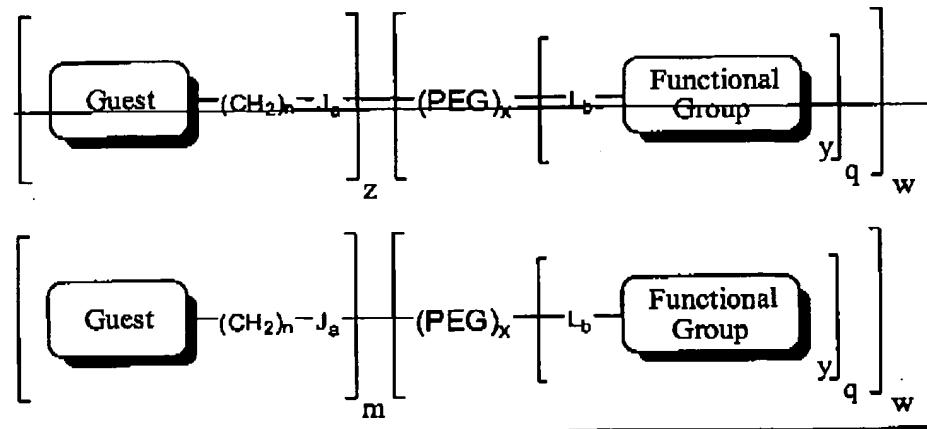
at least one polymer portion that increases solubility and/or imparts stabilization relative  
to a composition of the cyclodextrin-containing polymer and therapeutic agent  
alone;wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent  
are separate molecules.6. (previously presented) A composition of claim 5, wherein said therapeutic agent is  
selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a  
plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule,  
and mixtures thereof.7. (previously presented) A composition of claim 6, wherein said therapeutic agent is a  
polynucleotide.

8-11. (cancelled)

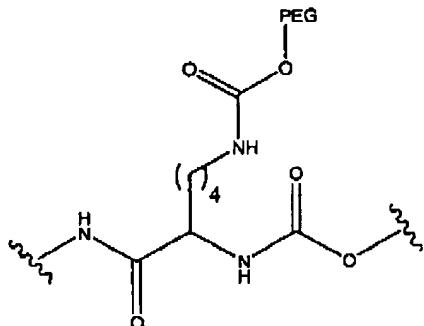
12. (currently amended) A composition of claim 5, wherein the complexing agent is a  
compound of the formula:

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wherein

 $J$  is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_c-\text{O}-\text{P}(=\text{O})(\text{O}-$  $(\text{CH}_2)_c-\text{Y}-\text{O}-$ , a peptide or polypeptide residue, or  
 $-\text{NH}-(\text{C}(=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}(=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

$\text{Y}$  is an additional host-guest functionality;

$\text{R}^1$  is  $-(\text{CH}_2)-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_a-\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where  $z$  varies from 2 to 500;

$\text{L}$  is  $\text{H}$ ,  $-\text{NH}$ ,  $-\text{NH}-(\text{C}(=\text{O})-(\text{CH}_2)_e-(\text{C}(=\text{O})-\text{CH}_2-$ ,  $-\text{S}(\text{=O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

$a$  is 0 or 1;

$b$  is 0 or 1;

$d$  ranges from 0 to 6;

$e$  ranges from 1 to 6;

$m$  ranges from 1 to 5;

$n$  ranges from 0 to 6;

$q$  ranges from 1 to 5;

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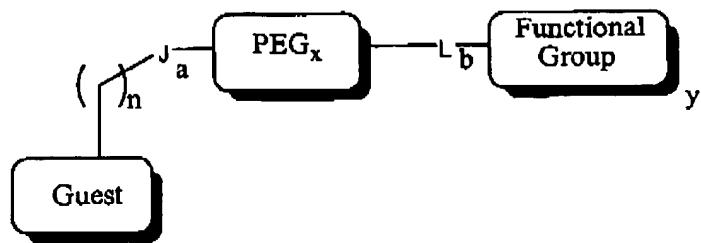
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w ranges from 1 to 5;

y is 1; and

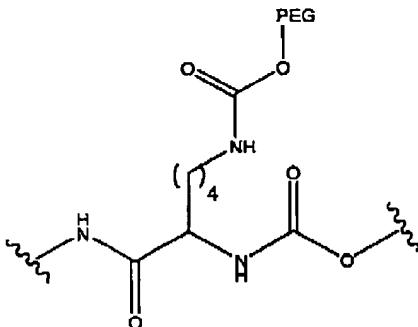
$x$  is 0 or 1.

13. (previously presented) A composition of claim 5, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}\cdot\text{P}(=\text{O})(\text{O}$



, a peptide or polypeptide residue, or

-NH-(C=O)-CH(R<sup>1</sup>)-NH-(C=O)-CH(R<sup>1</sup>)-NH-;

**Y is an additional host-guest functionality;**

$R^1$  is  $-(CH_2)_n-CO_2H$ , an ester or salt thereof; or  $-(CH_2)_n-CONH_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where  $z$  varies from 2 to 500;

L is H, -NH, -NH-(C=O)-(CH<sub>2</sub>)<sub>c</sub>-(C=O)-CH<sub>2</sub>-, -S(=O)<sub>2</sub>-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

$d$  ranges from 0 to 6;

e ranges from 1 to 6;

$n$  ranges from 0 to 6;

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y is 1; and

x is 0 or 1.

14. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

15. (previously presented) A composition of claim 5, wherein the polymer portion increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

16. (previously presented) A composition of claim 5, wherein the polymer portion stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

17. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a therapeutic agent reversibly bound to the complexing agent.

18. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a spacer group.

19-22. (cancelled)

23. (previously presented) A composition of claim 5, wherein at least one polymer portion of the complexing agent comprises PEG or derivatives thereof.

24-26. (cancelled)

27. (previously presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

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28. (previously presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.

29. (cancelled)

30. (previously presented) A composition comprising:  
a cyclodextrin-containing polymer,  
a therapeutic agent, and  
a complexing agent, comprising:  
at least one functional group,  
at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and  
at least one polymeric spacer group;  
wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

31. (previously presented) A composition of claim 30, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

32. (previously presented) A composition of claim 31, wherein said therapeutic agent is a polynucleotide.

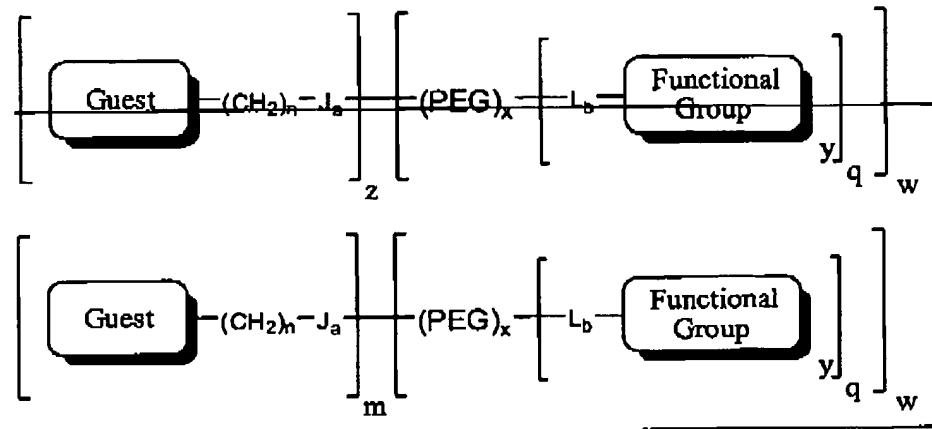
33. (cancelled)

34. (previously presented) A composition of claim 30, wherein at least one spacer group of the complexing agent comprises PEG or derivatives thereof.

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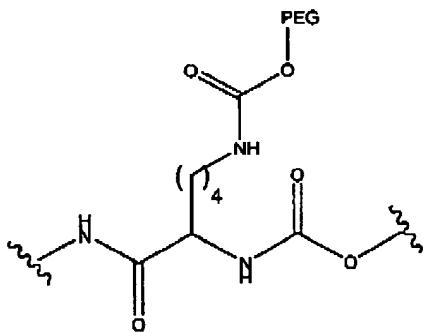
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35. (currently amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



$(\text{CH}_2)_e-\text{Y}-\text{O}-$ , a peptide or polypeptide residue, or  
 $-\text{NH}-(\text{C}= \text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}= \text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

$\text{R}^1$  is  $-(\text{CH}_2)-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_n-\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;

L is H,  $-\text{NH}$ ,  $-\text{NH}-(\text{C}= \text{O})-(\text{CH}_2)_e-(\text{C}= \text{O})-\text{CH}_2-$ ,  $-\text{S}(\text{=O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

m ranges from 1 to 5:

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n ranges from 0 to 6;

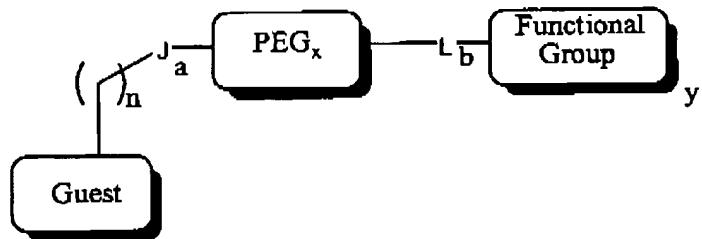
q ranges from 1 to 5;

w ranges from 1 to 5;

y is 1; and

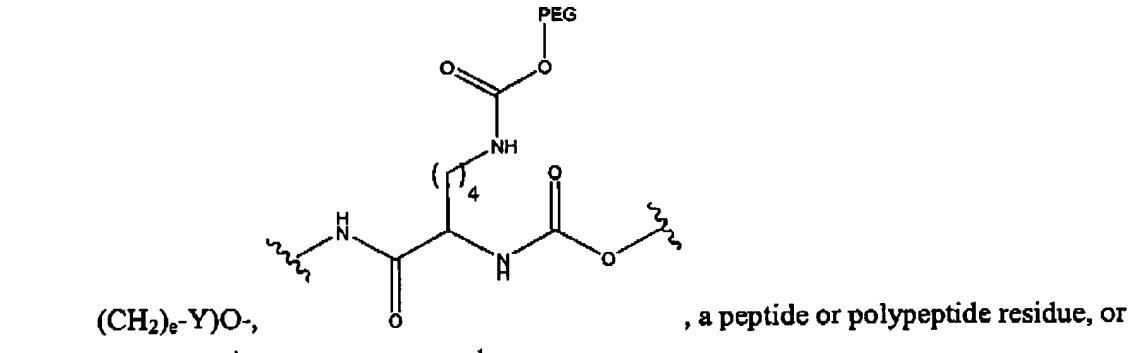
x is 1.

36. (previously presented) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is -NH-, -C(=O)NH-CH<sub>2</sub>)<sub>d</sub>-, -NH-C(=O)-(CH<sub>2</sub>)<sub>d</sub>-, -CH<sub>2</sub>SS-, -C(=O)O-(CH<sub>2</sub>)<sub>e</sub>-O-P(=O)(O-



Y is an additional host-guest functionality;

R<sup>1</sup> is -(CH<sub>2</sub>)-CO<sub>2</sub>H, an ester or salt thereof; or -(CH<sub>2</sub>)<sub>a</sub>-CONH<sub>2</sub>;

PEG is -O(CH<sub>2</sub>CH<sub>2</sub>O)<sub>z</sub>-, where z varies from 2 to 500;

L is H, -NH, -NH-(C=O)-(CH<sub>2</sub>)<sub>e</sub>-(C=O)-CH<sub>2</sub>-, -S(=O)<sub>2</sub>-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

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e ranges from 1 to 6;

n ranges from 0 to 6;

y is 1; and

x is 1.

37. (previously presented) A composition of claim 30, wherein at least one functional group includes a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

38. (previously presented) A composition of claim 30, wherein at least one functional group includes a moiety that increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

39. (previously presented) A composition of claim 30, wherein at least one functional group includes a moiety that stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

40. (previously presented) A composition of claim 30, wherein at least one functional group includes a therapeutic agent reversibly bound to the complexing agent.

41. (previously presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

42. (previously presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.